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No. 01-___

IN THE

Supreme Court of the United States

C.R. BARD, INC.,
Petitioner,

v.

W.L. GORE & ASSOCIATES, INC.,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

LAWRENCE H. MARTIN
FOLEY, HOAG & ELIOT LLP
1747 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 223-1200

PETER B. ELLIS *
FOLEY, HOAG & ELIOT LLP
One Post Office Square
Boston, MA 02109
(617) 832-1000

Counsel for Petitioner

*Counsel of Record

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

4988

QUESTIONS PRESENTED

What are the contours of a federal court's "holding"? Is the "holding" of a case narrowly confined to the relief expressly granted by the trial court, as the Third Circuit has ruled? Or, as the District of Columbia Circuit has ruled, does the "holding" of a case include issues of fact and law which are necessarily and indisputably subsumed within the court's express findings and rulings, such that the doctrine of issue preclusion would apply in any future proceeding?

CORPORATE DISCLOSURE STATEMENT

In accordance with Supreme Court Rule 29.6, petitioner C.R. Bard, Inc., a publicly traded company, states that it has no parent corporations nor is there any publicly held company that owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

C.R. Bard, Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS AND ORDERS BELOW

The opinion of the Court of Appeals (App., *infra*, 1a-4a) is not reported. The opinion of the District Court (App., *infra*, 5a-26a) is also not reported.

JURISDICTION

This petition seeks review of a decision of the United States Court of Appeals for the Third Circuit entered December 6, 2001. Jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1). This petition is timely pursuant to 28 U.S.C. § 2101(c) and Supreme Court Rule 13.

STATEMENT OF THE CASE

This case presents a fundamental issue of federal procedural law as to which two Courts of Appeal have reached radically different results: the scope and content of a federal court's "holding."

A. Factual Background

Petitioner C.R. Bard, Inc. ("Bard") and Respondent W.L. Gore & Associates, Inc. ("Gore") each manufacture and sell healthcare products, including products for the treatment of cardiovascular problems. Gore owned U.S. Patent No. 4,187,390 (the " '390 Patent," now expired) pertaining to certain materials formed of expanded polytetrafluroethylene ("ePTFE"). In 1984, Gore sued Bard (the "Initial Action") alleging that Bard's manufacture and sale of ePTFE vascular grafts infringed claims 9, 12, 16, 35 and 36 of the '390 Patent.[1]

Very shortly after the Initial Action was filed, Bard and Gore entered a settlement agreement (the "1984 Settlement Agreement"). Pursuant to that agreement, Bard agreed to the entry of final judgment and a permanent injunction, paid Gore $600,000 and agreed to destroy its remaining stocks of ePTFE grafts. Bard agreed also to one additional term, which later gave rise to the present suit.

At the time of the 1984 Settlement Agreement, Bard held license rights with respect to any patent which might issue from a then-pending patent application (the "Goldfarb Application"). Under Paragraph 3 of the 1984 Settlement

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[1] Patent "claims" set out the subject matter of the invention. *See* 35 U.S.C. § 112 (first sentence, second paragraph). They serve two functions: (1) they define the invention for the purposes of evaluating patentability, and (2) they define the scope of the patent for the purposes of determining infringement. Donald S. Chisum, 3 CHISUM ON PATENTS § 8.03, at 8-14 (2002). The '390 Patent contains a total of 77 claims, five of which were at issue in the Initial Action.

Agreement, Bard granted Gore an option to acquire a non-exclusive sub-license (the "Goldfarb Option") if a patent ultimately issued on the Goldfarb Application.

Bard, however, retained the right to revoke the Goldfarb Option if the five patent claims that Gore had asserted against Bard in the Initial Action were later "held" invalid. Specifically, paragraph 6 of the 1984 Settlement Agreement ("Paragraph 6") provided:

> In the event there is a final judgment of a United States court from which no appeal has been or can be taken and which ***holds invalid*** each and every one of the claims asserted against Bard, *i.e.*, claims 9, 12, 16, 35 and 36 of United States Patent No. 4,187,390, then Bard may [withdraw the Goldfarb Option].

(Emphasis added.)

On April 3, 1984, eight days after the effective date of the 1984 Settlement Agreement, Gore sued another company, International Medical Prosthetics Research Associates, Inc. ("IMPRA"), in the United States District Court for the District of Arizona (the "Arizona Action"). Gore alleged that IMPRA was infringing the '390 Patent by manufacturing and selling the same kind of ePTFE grafts as those formerly sold by Bard.

With the ink still wet on the 1984 Settlement Agreement, Gore elected to assert only claims 9, 12, 16 and 35 of the '390 Patent against IMPRA (*i.e.*, four of the five claims enumerated in Paragraph 6). It did not specifically assert claim 36.[2] After a two-and-a-half-month trial, the Arizona

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[2] This omission was conspicuous for two reasons. First, if IMPRA infringed claims 9, 12, 16 and 35, it also necessarily infringed claim 36. All of the elements of claim 36 are present in claims 9 and 35, and claim 36 introduces no novel elements. Moreover, Gore had asserted claim 36 in earlier litigation both against Bard and against a company that made products significantly different from those made by Bard and IMPRA.

district court issued an Amended Memorandum Opinion and Order, and an Amended Judgment (collectively, the "Arizona Final Judgment") on July 10, 1990 invalidating the '390 Patent. *See W.L. Gore & Assocs., Inc. v. IMPRA*, 16 U.S.P.Q.2d 1241 (D. Ariz. 1990). While the separate judgment document required by Federal Rule of Civil Procedure 58 refers on its face only to claims 9, 12, 16 and 35 of the '390 Patent (the claims Gore strategically chose to assert against IMPRA), the express holdings of the Arizona court's Memorandum Opinion swept far more broadly. Those holdings clearly signified the invalidity not only of claims 9, 12, 16 and 35, but also claim 36 and indeed every other claim of the '390 Patent. *At no point in the long history of this litigation has Gore seriously disputed this fact.* Gore has argued only that because the Arizona Final Judgment does not expressly refer to claim 36 by number, it did not "hold invalid" that claim, even though principles of issue preclusion/collateral estoppel would have prevented Gore from ever suing on the claim.

When Bard later learned of the Arizona Final Judgment,[3] it concluded that the Arizona Final Judgment had "held invalid"

Yet, it elected not to assert claim 36 against IMPRA, which made products functionally identical to Bard's.

[3] Gore appealed the Arizona Final Judgment to the United States Court of Appeals for the Federal Circuit. While the appeal was pending (and after oral argument), Gore and IMPRA settled the matter and agreed, at Gore's request, to a stipulated vacatur of the Arizona Final Judgment. Gore has argued that the vacatur precludes the Arizona Final Judgment from being considered a "final judgment" within the meaning of Paragraph 6. Bard argued that the vacatur had no effect on the condition subsequent of Paragraph 6. Because neither of the courts below addressed this issue, but based their rulings solely on the "holds invalid" language of Paragraph 6, the vacatur issue is not one that need be reached by this Court. The only issue presented by this Petition is the difference of opinion between the Third Circuit and the D.C. Circuit on the contours of a federal court's "holding."

claims 9, 12, 16, 35 *and* 36. Bard therefore informed Gore in May 1994 of its intention to revoke the Goldfarb Option pursuant to Paragraph 6 of the 1984 Settlement Agreement. Gore replied by denying that the conditions of Paragraph 6 had been satisfied by the Arizona Final Judgment because, according to Gore, claim 36 was unaffected by the Arizona court's decision. Bard thereafter brought this declaratory judgment action in the United States District Court for the District of New Jersey to determine the parties' rights. Jurisdiction was predicated on 28 U.S.C. § 1332.

B. Proceedings Below

At the close of discovery, Gore moved and Bard cross-moved for summary judgment on the question of whether the Arizona Final Judgment permitted Bard to invoke the condition subsequent embodied in Paragraph 6 of the 1984 Settlement Agreement.[4] Gore argued that the condition had not been satisfied because, on its face, the Arizona Final Judgment made no express mention of claim 36. Thus, Gore argued, the Arizona court's decision could not be said to have "held" claim 36 invalid.

Bard argued that because the Arizona court's express, detailed and binding findings of fact and rulings of law plainly applied to the entire '390 Patent, including claim 36 (a fact which Gore has never disputed), the Arizona court had "held" claim 36 invalid. Bard also argued that because standard principles of issue preclusion (collateral estoppel) would have barred Gore from asserting the validity of claim 36 in any other court, the only tenable conclusion was that claim 36 had been "held invalid" by the Arizona Final Judgment.

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[4] Gore had previously moved to dismiss Bard's declaratory judgment complaint for failure to state a claim upon which relief could be granted. The District Court granted that motion on July 26, 1997, but was subsequently reversed by the Third Circuit which remanded the case for discovery on July 13, 1998. Because those decisions are not here under review, Bard bypasses those decisions in this Petition.

Bard's argument as to the meaning of the term "holding" cited a then-recent ruling of the United States Court of Appeals for the Federal Circuit, *Teva Pharmaceuticals, USA, Inc. v. United States Food & Drug Administration*, 182 F.3d 1003 (D.C. Cir. 1999), which analyzed precisely the question presented here—the scope of a federal court's "holding." Consistently with the position advanced by Bard, the D.C. Circuit ruled in *Teva Pharmaceuticals* that a reliable way to know whether a court has rendered a "holding" on a particular issue is to determine whether preclusion principles would bar relitigation of that issue in the future.

On August 14, 2000, the District Court granted Gore's motion for summary judgment and denied Bard's cross-motion. The District Court decided that the Arizona Final Judgment had not "held" claim 36 invalid. Its decision was premised on the remarkable view that the content of the Arizona court's "holdings" must be determined solely by looking at the separate judgment document required by Federal Rule of Civil Procedure 58. (App. 17a-20a.) According to the District Court, it was impermissible to look for the Arizona court's holdings in its lengthy memorandum opinion setting forth the reasoning behind the Rule 58 judgment document. (*Id.*) The court also commented that the Arizona Final Judgment did not impliedly hold claim 36 invalid because

> [h]oldings of cases are explicit and they address the issues that have been presented to the court. Holdings are not implied from the similarity of the claims decided to other claims not asserted, especially in the area of patent litigation. Holdings are not derived by analogy from the issue-preclusive effect that a judgment may have.

(*Id.* at 22a.) Notably, the District Court made no attempt to reconcile its ruling with the directly contrary ruling of the D.C. Circuit in *Teva Pharmaceuticals*.

Bard timely noticed its appeal to the Third Circuit, which decided the case on December 6, 2001. Like the District Court, the Third Circuit decided that the Arizona Final Judgment had not "held" claim 36 invalid. The panel stated:

> Claim 36 was not held invalid by implication, because it is clear from the Arizona court's judgment that it was holding claims 9, 12, 16, and 35 invalid . . . We will not now decide that the Arizona court actually meant to "hold invalid" a claim that was never even placed into issue before it.

(*Id.* at 3a.) Just as the District Court had done, the Third Circuit adopted a mechanical, formalistic approach which examined only the face of the Arizona Final Judgment and did not analyze the substantive content of the Arizona court's findings and rulings. Nor did the Third Circuit confront the D.C. Circuit's contrary ruling in the *Teva Pharmaceuticals* case.

REASONS FOR GRANTING THE WRIT

This case illustrates the need for this Court to provide elucidation and guidance on a fundamental issue of federal civil procedure, as to which there is a clear difference of view between sister Circuits.

I. THE THIRD CIRCUIT'S DECISION CONCERNING THE SCOPE OF A COURT'S "HOLDING" CONFLICTS WITH THE DETERMINATION OF THE DISTRICT OF COLUMBIA CIRCUIT IN *TEVA PHARMACEUTICALS*

The writ should be granted because the Third Circuit has dramatically misunderstood a concept that lies at the very heart of the judicial process—*i.e.*, what constitutes a "holding." In so doing, it declined to follow clear and persuasive authority to the contrary from the District of Columbia Circuit.

To understand the error of the Third Circuit's approach, it is necessary first to understand precisely what the Arizona court actually decided. As demonstrated below, the Arizona court's analysis, findings and rulings were not limited to specific claims. Rather, they applied on their face to each and every claim of the '390 Patent, including claim 36.

The fact that the Arizona court held claim 36 invalid is most starkly demonstrated by its decision on the issue of enablement. For a patent claim to be "enabled," the detailed disclosure of the patent must teach "any person skilled in the art to which [an invention] pertains, or with which it is most nearly connected, [how] to make and use the same . . . ." 35 U.S.C. § 112. If it fails to do so, the claim is not enabled and is therefore invalid.

The '390 Patent contains 77 separate claims. Each and every one of those 77 claims pertains to a polymeric structure which has a specified "matrix tensile strength." [5] Claim 36 is no different in this regard from any other claim of the patent.

In the Arizona Action, the defendant IMPRA argued that the '390 Patent was not enabled because it did not teach one skilled in the art how to determine "matrix tensile strength." The Arizona district court agreed. It specifically held that the claims of the patent were not enabled because the patent "does not teach how any product produced in accordance with one of the claims should be tested to determine its matrix tensile strength," and "fails to disclose the preferred rate of stretching to achieve [the matrix tensile strength] element." 16 U.S.P.Q.2d at 1256.

Because the patent failed to provide anyone attempting to replicate the patented claims with sufficient information to determine what test should be applied and thus how to achieve the desired result, the Arizona court specifically

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[5] "Matrix tensile strength" appears on the face of certain claims and is incorporated by reference in all of the remaining claims.

found: "[t]he '390 Patent does not meet the enabling requirement because it does not specify the appropriate test for measuring tensile strength." *Id.* at 1260. The court's conclusions of law echoed this determination: "The '390 Patent did not meet the enablement requirements of 35 U.S.C. § 112." *Id.* at 1264.

It cannot be seriously disputed that the explicit findings and rulings that underlay this conclusion constituted a holding of the Arizona Final Judgment. Indeed, Gore's in-house counsel openly conceded at his deposition that the Arizona court's determinations with respect to the "matrix tensile strength" issue were part of its "holding."

As the text of the decision makes clear, the findings and rulings quoted above were not limited to any particular claims of the patent; rather, they applied to the patent as a whole. Indeed, because all claims of the '390 Patent incorporated the identical phrase "matrix tensile strength," there was no need for the findings and rulings to be so limited.

While the District Court below correctly noted that the amended Rule 58 document entered by the Arizona court referred only to the specific claims invoked by Gore in the Arizona Action, the Arizona court's "holdings" were not so limited. Because the identical phrase "matrix tensile strength" was included in each and every one of the '390 Patent's 77 claims, the Arizona court was entirely correct in ruling, in its Memorandum Opinion, that the patent as a whole was invalid. *Id.* at 1264.

The fact that the Arizona court's opinion does not expressly mention claim 36 by number is immaterial. The Arizona court did not confine its factual and legal determinations concerning lack of enablement to specific claims; rather, it spoke about "the '390 Patent" generally. Moreover, its determinations apply with as much force to claim 36 as to each and every one of the other claims of the '390 Patent (including claims 9, 12, 16 and 35). It borders on the absurd

to suggest that, even though the Arizona court explicitly held that the shared claim element "matrix tensile strength" was not enabled (a point which even Gore concedes), the court did not "hold" claim 36 invalid when that claim incorporated precisely the same claim element.

II. THE CORRECT APPROACH TO DETERMINING WHAT CONSTITUTES A "HOLDING" IS THAT OUTLINED BY THE DISTRICT OF COLUMBIA CIRCUIT IN *TEVA PHARMACEUTICALS*

As the District of Columbia Circuit ruled in *Teva Pharmaceuticals*, *supra*, a useful way to understand whether an earlier court decision encompassed a particular issue—and thus contained a "holding" on the issue—is to consider the law of issue preclusion (collateral estoppel). Issue preclusion bars the *re*litigation of issues actually decided in prior proceedings. *See United States v. Stauffer Chem. Co.*, 464 U.S. 165, 170 (1984) ("As commonly explained, the doctrine of collateral estoppel can apply to preclude relitigation of both issues of law and issues of fact if those issues were conclusively determined in a prior action.").

A. "Holdings" And Issue Preclusion Are Two Sides Of The Same Analytical Coin.

The fact that the notions of "holding" and "issue preclusion" are merely different ways of approaching the same concept is supported by both the academic literature and the case law. In discussing the word "holding," Professor Jane Ginsburg of Columbia University Law School has aptly observed:

> [T]o ask the question "What is the holding of a case?" is really to ask, "What fact situations can the rule of law of that case be said to govern?" *i.e.*, "As to what future cases does the decision of the case constitute binding

> authority?" . . . . [T]he answer to the question "What is the holding?" is a prediction that as to certain future fact situations the court will consider the decision governing.

Jane C. Ginsburg, LEGAL METHODS 93 (1996).

In *Teva Pharmaceuticals*, *supra*, the District of Columbia Circuit interpreted the word "holding" in precisely this manner. After observing that the term is not a rigid concept, the Court of Appeals noted that "the significance of a court's 'decision' or 'holding' often lies in its preclusive effect." 182 F.3d at 1008. In other words, to determine whether or not some action by a court constitutes a "holding," one inquires whether that action would be given preclusive effect by later courts. *See id.* (noting that when issue preclusion does not apply, there is no "holding").

In *Teva Pharmaceuticals*, the plaintiff company sought FDA approval to sell a generic form of a brand-name prescription drug. Under the applicable statute, Teva could do so if there was "a decision of a court *holding* the patent [to the name-brand drug] . . . invalid or not infringed." *Id.* (emphasis added). Teva had previously brought a declaratory judgment action against the patent owner. That suit, however, was dismissed for want of a case or controversy based on the patent owner's representation that it would not sue Teva.

Teva subsequently sought to have the FDA recognize that dismissal as the predicate "decision of a court holding the patent . . . invalid or not infringed" allowing Teva to market the generic drug. When the FDA refused to do so, Teva sought an injunction in federal district court. The district court ruled in favor of the FDA, but the D.C. Circuit reversed on appeal.

The court concluded that it would be arbitrary and capricious not to consider the first court's dismissal of Teva's complaint as a decision "holding the patent . . . invalid or not infringed" precisely because that decision would have

preclusive effect against the patent owner in any future suit. *Id.* at 1008-09. Thus, in direct contrast to the decision of the lower courts in this case, the D.C. Circuit held that it was arbitrary and capricious to decide that a ruling did not constitute a "holding" when that ruling would be entitled to preclusive effect in a subsequent action.

Two additional points about the *Teva* decision should be noted. First, the court in which Teva brought its original declaratory judgment action ruled only that "Teva lacks a reasonable apprehension of suit [by the patent owner]" and consequently that it lacked subject matter jurisdiction over the action. *Id.* at 1006. It did not expressly determine that the patent was "invalid" or "not infringed," the alternative predicates of the relevant statute. Nonetheless, the D.C. Circuit readily found that the prior action had "held" the patent "not infringed" within the meaning of the statute because the patent holder (based on its statement that it would not sue Teva) would forever have been estopped from suing Teva under the patent. *Id.* at 1009-10.

The D.C. Circuit stated: "[A] triggering 'court decision' need [not] explicitly hold the patent at issue is 'invalid' or is 'not infringed' in order [to satisfy the statute]." *Id.* at 1009. In sum, the D.C. Circuit had no difficulty finding that the prior action had implicitly "held" the patent "not infringed" even though the prior court nowhere expressly said so. Because non-infringement was the necessary consequence of what the court did find, the only reasonable conclusion was that the court had "held" the patent "not infringed." *See generally id.* at 1006-09.

It is also significant that the D.C. Circuit ruled that the dismissal of Teva's original complaint constituted a "holding" notwithstanding the fact that no other court had yet been called on to apply that holding preclusively. The mere fact that a future, hypothetical court would have to apply preclusion to the issue was sufficient to compel the

conclusion that the first court had already "held . . . the patent . . . invalid or not infringed." *See generally id.* at 1007-12. Indeed, when a second court applies the doctrine of issue preclusion, its determination is based on what the first court has already decided.

B. The Doctrine Of Issue Preclusion (Collateral Estoppel) Applies To Patent Claims Not Sued Upon.

When the approach taught by the District of Columbia Circuit for determining the scope of a court's "holding" is applied to the facts of this case, it is clear that the Arizona Final Judgment would have precluded Gore from asserting the validity of claim 36 in any future court action, and thus that the necessary invalidity of that claim was actually a "holding" of the Arizona court.

It is well settled that issue preclusion principles apply to the various claims of a patent with no less force than in other areas of the law. *See, e.g., Westwood Chem., Inc. v. United States*, 525 F.2d 1367 (Ct. Cl. 1975) (applying collateral estoppel to bar litigation of patent claims not specifically adjudicated in prior lawsuit when the unadjudicated claims presented identical issues); *Westwood Chem., Inc. v. Molded Fiber Glass Body Co.*, 498 F.2d 1115 (6th Cir. 1974) (same); *Technograph Printed Circuits, Ltd. v. Methode Elec., Inc.*, 484 F.2d 905 (7th Cir. 1973) (same); *see also Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313 (1971).

Bourns, Inc. v. United States, 537 F.2d 486 (Ct. Cl. 1976) makes the rationale for this rule clear. In applying issue preclusion to bar *re*litigation of patent claims not expressly addressed in a prior proceeding, the Court of Claims (the predecessor to the Federal Circuit) stated:

> It is the identity of the *issues* litigated and decided, and which were essential to the prior judgment, that determines whether the estoppel should be applied . . . .

> There is no reason to employ a different approach in a patent context by looking to the claims litigated instead of to the issues that were decided.
>
> . . . In reaching that conclusion, recognition is given to plaintiffs' arguments regarding due process and the further argument that each claim is to be presumed valid and treated as a complete and independent invention. However, by focusing on the issues of fact and law necessary to a resolution of the obviousness issue, . . . a determination can be made whether the unadjudicated claims present any new issues which, to afford due process, would require a trial on the merits or whether litigation on those claims would simply be a repetitious lawsuit over matters which have once been decided.

Id. at 491-92 (italics in original) (citations omitted). In sum, contrary to the assertions of the courts below, rulings on the validity of one patent claim can and do directly affect the validity of other claims that have not been sued on.

The Arizona district court expressly found and ruled that the concept of "matrix tensile strength" was insufficiently defined and therefore not enabled by the patent. This holding necessarily meant that each and every claim of the patent that incorporated a "matrix tensile strength" element (including claim 36) was invalid. Indeed, Gore has never challenged Bard's repeated assertions that, unless reversed, the Arizona Final Judgment would have forever precluded Gore from asserting claim 36 against an alleged infringer. Instead, Gore has mechanically insisted (and the courts below have agreed) that solely because the Arizona Final Judgment did not specifically mention claim 36 by number, that claim was not "held" invalid. As argued above, and as the D.C. Circuit earlier ruled in an analogous situation, this position fundamentally misconstrues the concept of a "holding."

III. THE CONFLICT IN APPROACHES ILLUSTRATED BY THE THIRD CIRCUIT'S DECISION IN THIS CASE AND THE DISTRICT OF COLUMBIA CIRCUIT'S DECISION IN *TEVA PHARMACEUTICALS* ILLUSTRATES THE NEED FOR GUIDANCE FROM THIS COURT

The concept of "holding" is of central importance in American jurisprudence. Indeed, it underlies the very principle of *stare decisis*. Bard respectfully submits that the Third Circuit's decision, echoing that of the trial court, illustrates the extent of judicial confusion that still exists with respect to the terms "holds" and "holding," and stands in stark contrast to the intellectually-nuanced analysis engaged in by the District of Columbia Circuit. By granting this petition, the Court would have an opportunity to resolve, for future courts and litigants, the correct approach to determining what constitutes a judicial "holding."

In this case, both the District Court and the Third Circuit adhered to a narrow, mechanistic interpretation under which "holdings" are limited to the express statements made on courts' Rule 58 judgment documents. In so doing, they not only broke ranks with the D.C. Circuit, but departed from the jurisprudence of this Court (and virtually every other federal court) showing that "holdings" need not be explicit. Even the most cursory research reveals literally thousands of cases discussing and applying "implicit holdings." *See, e.g., United States v. Sioux Nation of Indians*, 448 U.S. 371, 407 (1980) (observing that the Court had earlier "implicitly held" that "Congress' mere waiver of the res judicata effect of a prior judicial decision rejecting the validity of a legal claim against the United States does not violate the doctrine of separation of powers.").

To the best of Bard's knowledge, prior decisions of this Court have not squarely addressed the issue of how to

determine the "holding" of a prior case. A decision in this case would bring greater analytical clarity to an important area of procedural law.

CONCLUSION

For all the foregoing reasons, Bard's Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

LAWRENCE H. MARTIN
FOLEY, HOAG & ELIOT LLP
1747 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 223-1200

PETER B. ELLIS *
FOLEY, HOAG & ELIOT LLP
One Post Office Square
Boston, MA 02109
(617) 832-1000

Counsel for Petitioner

* Counsel of Record